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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/981,665	11/05/1997	STAN CIPKOWSKI	3000	8326
7590 EDMUND M JASKIEWICZ 1730 M STREET NW SUITE 400 WASHINGTON, DC 20036			EXAMINER GRUN, JAMES LESLIE	
			ART UNIT 1641	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

08/981,665

Applicant(s)

CIPKOWSKI, STAN

Examiner

JAMES L. GRUN

Art Unit

1641

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Statement(s) (PTO/SF/42)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

The request for reconsideration filed 24 August 2009 is acknowledged and has been entered. Claims 16, 18, and 19 remain in the case.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, and failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Claims 16, 18, and 19 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As set forth with regard to the claims as now amended, the specification, as originally filed, does not provide support for a sample **contacting portion on the exposed surface** (i.e., front) **of the test strip** so that liquid sample flows through the sample opening in the thin flat member strip holder and contacts the **exposed surface** (i.e., front) of the sample portion directly beneath (i.e., registering with) the opening. Again, as set forth, applicant provides no guidance in the specification for certain particulars of the test strip structure. Again, applicant merely discloses that specimen is able to contact the “absorbent or sample portions” of the test strips through the sample openings of the card (see e.g. page 12). There is no disclosure that these

portions are on, or only on, the surface. Moreover, there is no specific teaching in the instant specification regarding whether the instantly exemplified test strips do or do not include the conventional backing or sandwiching with plastic taught in May et al. (WO 88/08534). Such sandwiching would affect the size and shape of the “sample portion” and, as taught in some conventional test strip references (see e.g. Lee-Own et al., US 5,500,375), the “sample portion” may only be the cut end and, therefore, not necessarily located on the front surface. Thus, there is nothing to support that the “sample contacting portions” of the test strips are exposed on the test strip **surface** beneath the opening in the thin flat member as is now claimed. Inclusive disclosure of several formerly commercially available test strips does not provide explicit or implicit indication to one of skill in the art that the invention was contemplated as limited to particular undisclosed structural interrelationships selected from a range of possible designs. Further, the disclosure that the test strip “consists of a membrane strip onto which a drug conjugate has been immobilized” (see page 13) is not dispositive of the issue because further components of the test strip are either previously or later recited (e.g. colloidal gold-antibody complex, a control band or line, absorbent portion, etc.) so that it is clear that applicant did not intend “consists of” in this context as limiting the test strip structure. Moreover, the examiner would note that essentially the entire test strip contacts sample (see e.g. specification page 13 wherein it is admitted that sample contacts the test line having immobilized drug conjugate) so that a “sample contacting portion” would not appear to be clearly described in the specification. If it is applicant’s intent that the entire bottom portion of the test strip up to the maximum line is to be construed as the now recited “sample contacting portion” because that is the portion submerged in sample (see e.g. page 9 and item 32 in Fig. 3) whether it is sandwiched with plastic

or not, then it is clear that the openings in the test card as depicted in Figs. 9 or 11 do not fully expose (i.e. register with) “the sample contacting portion” because the “MAX LINE” defining the boundary of the sample contacting portion is not within the exposed portion. Although one of skill in the art might realize from reading the disclosure that absorbent or sample receiving portions on the exposed (i.e., front) **surface** of the test strips are useable in the invention or that a sample contacting portion may be fully exposed by a sample opening, such possibility of use does not provide explicit or implicit indication to one of skill in the art that such were originally contemplated as part of applicant's invention and such possibility of use does not satisfy the written description requirements of 35 U.S.C. § 112, first paragraph. Note that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement. Applicant is again requested to direct the Examiner's attention to specific passages where support for these newly recited limitations can be found in the specification as filed or is required to delete the new matter.

Applicant's arguments filed 24 August 2009 have been fully considered but they are not deemed to be persuasive for the extensive reasons of record.

Applicant again urges that the disclosures that are also noted by the examiner, at page 12 and at least in Fig. 9, provide support for the invention as is now claimed. This is not found persuasive for the reasons of record and as set forth above regarding the deficiencies of these disclosures to support structural/functional elements specifically of the test strip(s) (attached longitudinally to a thin flat member strip holder) as are now claimed that are entirely lacking description in the specification as filed.

Applicant again urges that some conventional test strips are configured to have a sample contacting portion on the front surface and that such a possibility of use provides support for the claiming of any such embodiments. This is not found persuasive because, as set forth, test strips have a broad range of possible designs and the inclusive disclosures of several formerly commercially available test strips, for which no evidence has been provided of a surface sample contacting portion, have not been found as providing explicit or implicit indication to one of skill in the art that the invention was contemplated as limited to the particular undisclosed structural interrelationships selected from a range of possible designs as are now claimed. Notwithstanding applicant's allegations to the contrary, disclosure of a sample portion exposed by an opening does not provide inherent support for a sample contacting portion on the surface of the exposed portion and does not provide support that the entire sample contacting portion is exposed by the opening. The case of *In re Ruschig* (379 F.2d 990, 154 USPQ 118 (CCPA 1967)) makes clear that one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say "here is my invention." In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure. See *id.* at 994-95, 154 USPQ at 122; *Fujikawa*, 93 F.3d at 1570-71, 39 USPQ2d at 1905; *Martin v. Mayer*, 823 F.2d 500, 505, 3 USPQ2d 1333, 1337 (Fed. Cir. 1987) ("It is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure Rather, it is a question whether the application necessarily discloses that particular device.'") (quoting *Jepson v. Coleman*, 314 F.2d 533,536, 136 USPQ 647, 649-50 (CCPA 1963)).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 18, and 19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 16, 18, and 19, "the fluid sample" at line 14 lacks antecedent basis.

Applicant's arguments filed 24 August 2009 have been fully considered but they are not deemed to be persuasive.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

(c) Subject matter developed by another person, which qualifies as prior art only under one or more subsections (e), (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 16, 18, and 19 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over May et al. (WO 88/08534) in view of Sun et al. (US 5,238,652), and further in view of Boger et al. (US 4,518,565) for reasons of record.

Applicant's arguments filed 24 August 2009 have been fully considered but they are not deemed to be persuasive for the extensive reasons of record.

Applicant's arguments regarding undisclosed features of the test strip(s) attached longitudinally to the thin flat member strip holder were again not found persuasive for the extensive reasons of record set forth under 35 USC 112 and incorporated herein.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, applicant again urges that the references of May et al. or Boger et al. fail to specifically exemplify combinations of elements of the invention as are now claimed. This is not found persuasive because applicant's argument does not address the reasons and arguments of record regarding the obviousness and motivation for combinations of features from the references as combined. It is again noted that Boger et al. teach reagent area-exposing openings in a holder, which can be made of cardboard, for holding multiple test strips which can be for conducting immunochemical tests. Arguments against individual aspects of the references which were not relied upon in the rejection and which do not serve to teach away from the invention as a whole, such as particular structural elements of various particular embodiments of the test strips of Boger et al., were again not found persuasive for the reasons of record. For the reasons of record, May et al. and Sun et al. teach lateral flow immunoassay test strips. Applicant also clearly admits that the test strips for performance of the immunoassay were commercially available (see pages 8-9). As also set forth, May et al. specifically exemplify casings having apertures in the front or end of the casing for sample application, and specifically teach that the dry porous carrier communicates directly, or indirectly via a porous receiving member, with the exterior of the casing such that

sample can be applied to the porous carrier (see e.g. page 3, or claims) and that combinations of features of the specifically exemplified embodiments were contemplated. Notwithstanding applicant's assertions to the contrary, either the porous carrier or the porous receiving member of May et al., which also may be present on the undisclosed structure of applicant's test strips, may **directly** contact the sample through a sample application aperture in the casing. Thus, it is not clear how one could assert that the reference of May et al. teaches away from sample contacting the test strip. For example, notwithstanding applicant's assertions to the contrary, the opening 601 in Fig. 11 is above the absorbent portion of the porous receiving member optionally provided as part of the test strip linked to the porous carrier. For the reasons of record, one would have been motivated to provide a casing such as that depicted in Fig. 11 for a nitrocellulose test strip as depicted in Fig. 1 in view of the teachings in May et al. that such combinations were possible and that the sample receiving portion thereof was not sufficiently robust to protrude from a casing and one would have expected the combination to function as desired. Moreover, notwithstanding applicant's arguments to the contrary, there is nothing found in the disclosure of May et al. that excludes bathing an entire sample receiving portion of a dry porous carrier without a porous receiving member, as depicted in Fig. 1, when contacted with a sample in a casing such as that depicted in Figs. 5 or 6 or 11. The shape of the apertures and their placement on the end or front of the casing would seem obvious matters of design choice.

Applicant again urges that the declaration under 37 CFR 1.132 of Keith Palmer filed 29 August 2006 provides evidence of secondary considerations of nonobviousness because of the commercial success noted in the declaration of the RAPID DRUG SCREEN[®] test kit. This is not found persuasive because it is not clear that the commercial success of the kit, comprising a

test card and a specimen container with a slotted lid which accommodates the test card, is due merely to the test card, as instantly claimed, and not to the combination as patented (see US 5,976,895).

In response to Applicant's implied arguments that there are no specific suggestions to combine the references, the examiner recognizes that references cannot be arbitrarily combined and that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the common knowledge or common sense generally available to one of ordinary skill in the art. See: *In re Nomiya*, 184 USPQ 607 (CCPA 1975); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); or, *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). However, there is no requirement that the claimed invention or a motivation to make the modification be expressly articulated in any one or all of the references. The test for combining references is what the combination of disclosures, taken as a whole, would suggest to one of ordinary skill in the art. See: *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); or, *In re McLaughlin*, 170 USPQ 209 (CCPA 1971). References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. See: *In re Bozek*, 163 USPQ 545 (CCPA 1969). A person of ordinary skill in the art, using common knowledge and common sense, is capable of fitting the teachings of multiple references together like pieces of a puzzle, regardless of the specific problem being addressed by the individual references. Any need or problem known at the time of the invention can provide a reason for combining elements of the different references. A person of ordinary skill in the art is also a person of ordinary creativity. In this case, for the reasons of record,

ample motivations to combine the references with an extremely reasonable expectation of success have been set forth. As set forth, it would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have constructed the device of May et al., i.e. test strip(s) in a holder, as modified employing combinations of features of the specifically exemplified device embodiments therein as well as the ridges or other means which facilitate the preferred parallel alignment of multiple strips in the holder with reagent area-exposing openings as taught in Boger et al., with reagents in a competitive immunoassay format for determination of drugs of abuse because May et al. teach the general applicability of their devices for determinations of analytes such as drugs with selection of appropriate binding reagents and Sun et al. teach that constructions wherein antigen in sample and antigen immobilized on the test strip compete for binding with mobile latex-labeled antibodies were well known alternatives in the art for determinations of drugs of abuse on immunoassay test strips, preferably with a plurality of test strips for different drugs of abuse configured in a parallel arrangement in a holder with reagent area-exposing openings for the determination of at least five drug of abuse analytes in a single device.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN

THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 11 a.m. to 7 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya, SPE, can be contacted at (571) 272-0806.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. L. G./
James L. Grun, Ph.D.
Examiner, Art Unit 1641
December 28, 2009

/Shafiqul Haq/
Primary Examiner, Art Unit 1641